K113776

510K Summary

AUG 8 2012

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807-92(c).

1. **The submitter of this pre-market notification is:**

Symmetry Medical Inc.
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Contact :
Robert Johnson
Director of Quality
Email: rob.johnson@symmetrymedical.com

2. **Device Name:**

Common Name	Sterilization Container
Trade Name	FlashPak® or FlashPak® Sterilization Container System

3. **Device Classification Information:**

Device Panel	Classification	Prod Code	Description
General Hospital	880.6850 Class II	FRG	Wrap, Sterilization

4. **Predicate Device**

Name	FlashPak® Sterilization Container System
Classification	Class II
510(k) Number	K871202

5. **Device Description:**

The FlashPak Container System consists of a family of rigid reusable containers that provide an effective sterilization packaging method for surgical instruments requiring flash steam sterilization. Each FlashPak system is comprised of an upper lid that seals by means of a silicone gasket and latches to a lower base creating a totally enclosed environment. A stainless steel wire basket is utilized inside the container to facilitate handling of sterilized items. The lid and base incorporate pressure actuated valves that open to allow sterilant to enter the container during the pressurization portion of the sterilization cycle and then close to seal the container once the cycle is over so the container and its contents can be removed from the sterilizer and immediately transported to the point of use without the risk of recontamination.

6. Intended Use Statement:

FlashPak® is a reusable rigid container system to be used during flash sterilization by hospitals and healthcare facilities. It is intended to enable flash sterilization of the enclosed devices and prevent recontamination during immediate transport to the point of use. The container is compatible with gravity-displacement flash sterilization using a 10 minute cycle at 132° C and with pre-vacuum flash sterilization using a 4 minute cycle at 132° C. FlashPak is recommended for surface sterilization of stainless steel instruments and for lumens with the following limits: gravity-displacement (5.5mm inner diameter or larger and up to 184mm in length), pre-vacuum (1mm inner diameter or larger and up to 203mm in length).

7. Summary of Technological Characteristics of the Device Compared to the Predicate Device

ELEMENT	PREDICATE	NEW DEVICE	DISCUSSION
Intended Use	Note: No formal intended use statement was included in the K871202 submission. The following is taken from the description: 'The product is a container system to be used in the Flash Sterilizer to sterilize instruments and to prevent recontamination while the instruments are transported to the operating room.'	FlashPak® is a reusable rigid container system to be used during flash sterilization by hospitals and healthcare facilities. It is intended to enable flash sterilization of the enclosed devices and prevent recontamination during immediate transport to the point of use. The container is compatible with gravity-displacement flash sterilization using a 10 minute cycle at 132° C and with pre-vacuum flash sterilization using a 4 minute cycle at 132° C. FlashPak is recommended for surface sterilization of stainless steel instruments and for lumens with the following limits: gravity-displacement (5.5mm inner diameter or larger and up to 184mm in length), pre-vacuum (1mm inner diameter or larger and up to 203mm in length).	Intended Use statement is equivalent albeit additional relevant detail has been included.
Material Composition	Ultem Base and Lid	Radel Base and Lid	Both rigid & durable
	Ultem Instrument Tray	SS Instrument Basket	Both rigid & durable
	SS Latches	SS Latches	Same
	Silicone Gasket and Valve Seal	Silicone Gasket and Valve Seal	Same
	SS Hardware	SS Hardware	Same
	SS Microfilter Disk	SS Microfilter Disk	Same
	N/A	Silicone Lid Vent	Same as gasket/seal
	Radel Valve Body	SS Bellows	Both rigid & durable
	Silicone Diaphragm	N/A	N/A
	RTV Silicone Sealant	N/A	N/A
	N/A	SS Bracket	Rigid & durable

Physical Properties	Materials are compatible with steam sterilization. Materials are commonly used in sterilization trays and cases.	Same as predicate	Equivalent
Chemical Properties	Materials are non-reactive and are compatible with recommended cleansers. Materials are commonly used in sterilization trays and cases.	Same as predicate	Equivalent
Configurations/ Dimensions	Container Sizes: (10″ x 7″ x 2″) (10″ x 10″ x 2″)	Container Sizes: (11″ x 11″ x 7″) #9020 (20″ x 11″ x 8″), #9030 (24″ x 11″ x 9″) #9040 (24″ x 13″ x 9″) #9050	Subject device offers larger sizes within the product family that all function in the same manner.
Air Permeance	N/A	N/A	N/A
Percent of Surface Perforations	N/A	N/A	N/A
PERFORMANCE	**PREDICATE**	**NEW DEVICE**	**DISCUSSION**
Sterilant Penetration	Sterilization Efficacy Gravity-displacement Cycle: • 10 minutes at 132°C(270°F) for porous and cannulated devices Dynamic-air-removal Cycle • 5 minutes at 132°C(270°F) for porous and cannulated devices Sterilant Penetration Thermal mapping studies demonstrating container temperature closely matches sterilizer chamber.	Sterilization Efficacy Gravity-displacement Cycle: • 10 minutes at 132°C(270°F) for porous and cannulated devices Dynamic-air-removal Cycle • 4 minutes at 132°C(270°F) for porous and cannulated devices Sterilant Penetration Thermal mapping studies demonstrating container temperature closely matches sterilizer chamber.	Equivalent
Microbial Barrier Properties (Packaging Integrity)	The container completely encapsulates the items sterilized inside and prevents recontamination during transport to the point of use immediately after sterilization.	Same as predicate	Equivalent
Material Compatibility	Materials used are compatible with the recommended sterilization method and cleansers.	Same as predicate	Equivalent
Toxicological Properties (Biocompatibility, including Sterilant Residue Limits)	Materials used are either medical grade polymers or stainless steel. Instruments placed in the container only come in contact with the Ultem tray. No patient contact.	Cytotoxicity per ISO 10993-5 Irritation per ISO 10993-10	Equivalent
Shelf Life	N/A FlashPak is intended for flash sterilization and immediate use	Same as predicate	Equivalent

Drying Time	N/A FlashPak is intended for flash sterilization and immediate use	Same as predicate	Equivalent
Aeration time	N/A	N/A	

8. The major modifications are as follows:

   - Re-designed pressure actuated valve to be more robust. The valves, one in the container lid and one in the container base, allow ingress and egress of sterilant. The new valve design which is hermetically sealed also eliminated the need to periodically equalize the internal valve pressure to ambient due to porosity of the predicate valve materials.
   - Changed base and lid material from vacuum formed Ultem to vacuum formed Radel which performs in a similar manner within steam sterilization environments.
   - Added larger size containers to the FlashPak product family of containers.
   - Added a silicone rubber lid vent button that can be used by the healthcare personnel to release any vacuum created within the container during cooling thereby making it easier to remove the lid.
   - Changed the inner instrument tray from Ultem to a stainless steel wire basket.
   - Modified the lid gasket profile from one with two sealing ridges to one with a smooth conforming edge design.
   - Modified the container latches from hinged lock down clamps to a spring steel clip.
   - Modified the shape of the container body to allow more room for instruments.
   - Modified labeling on the device and in the IFU to include more extensive instructions.

   These recognized differences between the subject container and the predicate are intended to make the device more robust and better meet users needs; they do not represent changes that effect the safety or effectiveness of the device.

9. Testing to applicable standard, ANSI/AAMI ST77:2006 – "Containment Devices for Reusable Medical Device Sterilization" has been completed with acceptable outcomes. The following testing has been performed:
   - Sterilization validation – gravity-displacement mode using a half cycle of the recommended parameters for flash sterilization demonstrating a 10^{-6} SAL for the half cycle.
   - Sterilization validation – dynamic-air-removal (pre-vacuum) mode using a half cycle of the recommended parameters for flash sterilization demonstrating a 10^{-6} SAL for the half cycle.
   - Biocompatibility testing including cytotoxicity and irritation.
   - Thermal mapping studies for both gravity-displacement and pre-vacuum sterilization.
   - Performance Testing – handle strength testing and valve life testing

   These tests demonstrate that the FlashPak Sterilization Container System functions as intended and is substantially equivalent to the legally marketed predicate device.

10. Substantial Equivalence:

The FlashPak Sterilization Container System has the same indications for use as the predicate device, FlashPak Container System. While there are technological differences between the devices, such as the device material and dimensions, these differences do not raise new types of safety and effectiveness questions when all listed warnings and cautions are followed. The FlashPak Sterilization Container System is substantially equivalent to the marketed FlashPak Container System.

Symmetry Medical Inc.

Robert Johnson, Director of Quality

02-16-2012
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Robert Johnson
Symmetry Medical
Director of Quality
61 John Vertente Blvd
New Bedford, Massachusetts 02745

AUG 8 2012

Re: K113776
Trade/Device Name: FlashPak® Sterilization Container System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: July 9, 2012
Received: July 16, 2012

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

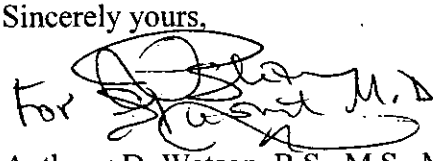
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
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Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): _K113776

Device Name: _FlashPak® Sterilization Container System

Indications for Use:

FlashPak® is a reusable rigid container system to be used during flash sterilization by hospitals and healthcare facilities. It is intended to enable flash sterilization of the enclosed devices and prevent recontamination during immediate transport to the point of use. The container is compatible with gravity-displacement flash sterilization using a 10 minute cycle at 132° C and with pre-vacuum flash sterilization using a 4 minute cycle at 132° C. FlashPak is recommended for surface sterilization of stainless steel instruments and for lumens with the following limits: gravity-displacement (5.5mm inner diameter or larger and up to 184mm in length), pre-vacuum (1mm inner diameter or larger and up to 203mm in length).

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth T. Mansie-Wells

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113776